As further stated in the Notice, and as confirmed by the Examiner in a telephone interview with the undersigned and Mr. Steven Petersen on January 13, 2003, originally filed claims 1-27 were directed to a system for the production of autologous thrombin. During the interview, the Examiner indicated it would be permissible to pursue system claims to the production of autologous thrombin. Accordingly, such system claims have been added herein as new claims 33-52. As a result of this Amendment, claims 33-52 remain pending for the Examiner's consideration. No new matter has been added by this amendment. Reexamination and reconsideration of the application, as amended, are requested.

A. 35 U.S.C. § 101 Provisional Rejection Addressed

In the previous Office Action, Paper No. 8, claims 1-20, 25 and 26 were provisionally rejected under 35 U.S.C. § 101 as claiming the same invention as that of claims 1-20, 21 and 22, respectively, of copending application 09/833,234. Claims 1-20, 25 and 26 were cancelled in the Amendment filed November 26, 2002. It is further asserted that newly presented claims 33-52, which are directed to a system for the production of autologous thrombin, do not claim the same invention as that of claims 1-20, 21 and 22, respectively, of copending application 09/833,234, which are directed to a system for the production of autologous platelet gel.

B. Provisional Rejection under Obviousness-Type Double Patenting Addressed

In the previous Office Action, Paper No. 8, claims 21-24 and 27 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of copending application 09/833,234. Claims 21-24 and 27 were cancelled in the Amendment filed November 26, 2002, thereby obviating this rejection.

C. 35 U.S.C. § 102(f) and (g) Rejections Addressed

In the previous Office Action, Paper No. 8, claims 1-20 were rejected under 35 U.S.C. § 102(f) or 102(g) because the applicant did not invent the claimed subject matter. Claims 1-20 were cancelled in the Amendment filed November 26, 2002, thereby obviating this rejection.

D. 35 U.S.C. § 102(b) and (e) Rejections Addressed

1. In the previous Office Action, Paper No. 8, claims 1-27 were rejected under 35 U.S.C. § 102(b) or (e) as being anticipated by Holm et al. The Office Action pointed to

Figures 1-3 and the Example to support this rejection. Claims 1-20 were cancelled in the Amendment filed November 26, 2002, thereby obviating this rejection. Further, it is asserted that newly presented claims 33-52 are not anticipated by Holm et al.

Holm does not teach every element of claims 33-52 and therefore does not anticipate claims 33-52. Independent claim 33 is directed to a system for the production of autologous thrombin comprising at least a first chamber for containing a portion of an inactivated blood component isolated by centrifugation of a blood sample in a reservoir. The chamber is not part of the centrifuge, nor is the chamber ever used in the centrifuge for further processing of the inactivated blood component. Rather, the purpose of the first chamber is to activate a first portion of the inactivated blood component, thereby forming a coagulated blood component comprising autologous thrombin and a clot. Dependent claim 34 further defines the system as comprising a filter for separating the autologous thrombin from the clot.

Holm does not teach a system for preparing an autologous thrombin. On the contrary, Holm describes a method and device for isolating a fibrin monomer from blood. As described in column 9, line 3 through column 11, line 56, the Holm et al. method comprises first adding whole blood to a first chamber of a multi-chambered device, placing the device in a centrifuge, and centrifuging the whole blood to separate the plasma from the red blood cells. While centrifuging, a piston within the device is raised to transfer the plasma to a second chamber (the "reaction chamber") positioned below the first chamber within the same device. A thrombin-like enzyme is added to the second chamber via a capsule contained within the second chamber to cause a non-crosslinked fibrin polymer to form within the second chamber, and continued centrifuging causes the polymer to form a layer on the walls of the second chamber. The centrifuging is stopped, the remaining plasma is then transferred back to the first chamber, and a buffer solution is added to the second chamber along with centrifugal agitation to dissolve the polymer to provide a fibrin monomer-containing solution. A biotin solution is added to the monomer solution to bind excess enzyme. The solution is then transferred to a third chamber within the same device. The solution in the third chamber is then transferred to a fourth chamber within the same device through an avidin filter to separate the fibrin monomer from the biotin-enzyme complex. The fibrin monomer is then removed from the fourth chamber via the same syringe.

Accordingly, Holm does not teach every element of newly presented claims 33-52, and therefore Holm does not anticipate claims 33-52.

2. In the previous Office Action, Paper No. 8, claims 1-27 were rejected under 35

U.S.C. § 102(b) or (e) as being anticipated by Antanavich et al. The Office Action pointed to the claims of Antanavich et al. for support of this rejection. Claims 1-20 were cancelled in the Amendment filed November 26, 2002, thereby obviating this rejection. Further, it is asserted that newly presented claims 33-52 are not anticipated by Antanavich.

In contrast to the present invention, Antanavich discloses a system for producing a platelet-rich plasma concentrate, which can then be combined with calcium (and optionally with bovine or human thrombin). The platelet rich plasma concentrate is prepared using an apparatus having a first chamber containing a first separator for separating plasma and platelets from whole blood, and a second chamber in fluid communication with the first chamber and containing a concentrator for concentrating the platelet rich plasma. The second chamber also contains a second separator (i.e., a filter) for separating the concentrated platelet rich plasma from the concentrator (column 15, lines 45-59). The first separator is, for example, a foam or a porous wall that traps the red and white blood cells (column 15, line 60 through column 16, line 5). The concentrator is material that absorbs water, electrolytes and small proteins in the plasma.

Thus, Antanavich does not disclose a system for producing autologous thrombin as taught and claimed in the present invention, and specifically does not teach a system comprising a chamber for receiving and reactivating blood component to form a clot and thrombin. Further, Antanavich does not teach a filter for separating the thrombin from the clot. Accordingly, Antanavich does not teach every element of claims 33-52, and therefore the Antanavich does not anticipate claims 33-52 of the present case.

3. In the previous Office Action, Paper No. 8, claims 1-27 were rejected under 35 U.S.C. § 102(b) as being anticipated by Morse et al. (WO 91/09573), however, the Office Action did not reference anything in the Morse et al. disclosure to support this rejection. Claims 1-20 were cancelled in the Amendment filed November 26, 2002, thereby obviating this rejection. Further, it is asserted that newly presented claims 33-52 are not anticipated by Morse.

In contrast to the present invention, Morse teaches a system for collecting a blood coagulation factor (fibrinogen and Factor XIII). The system has a first container for receiving and separating whole blood into plasma by centrifugation, a second container for receiving the plasma, and a conduit means for transferring the plasma from the first to the second container. The second container contains an agent to effect precipitation of the blood coagulation factor. Centrifugation of the second container separates the precipitated

coagulation factor from the plasma. The second container is designed to facilitate separation of the blood coagulation precipitate from the plasma.

Thus, Morse does not disclose a system for producing autologous thrombin as taught and claimed in the present invention, and specifically does not teach a system comprising a chamber for receiving and reactivating blood component to form a clot and thrombin. Further, Morse does not teach a filter for separating the thrombin from the clot. Accordingly, Morse does not teach every element of claims 33-52, and therefore the Morse does not anticipate claims 33-52 of the present case.

CONCLUSIONS

It is believed that all claims now pending in this patent application, as amended and described above, are now allowable. Therefore, it is respectfully requested that the Examiner reconsider his rejections and to grant an early allowance. If any questions or issues remain to be resolved, the Examiner is requested to contact the undersigned at the telephone number listed below. No fees are believed to be required for filing this Amendment and Remarks. However, should any fee be required, please charge Deposit Account No. 50-1123.

Respectfully submitted,

Jan. 23, 2003
Dated

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MARKED UP VERSION SHOWING CHANGES MADE TO TITLE

Please amend the title as follows:

[METHOD] SYSTEM FOR THE PRODUCTION OF AUTOLOGOUS THROMBIN

CLEAN VERSION OF AMENDED TITLE

Please replace the title with the following:

SYSTEM FOR THE PRODUCTION OF AUTOLOGOUS THROMBIN

MARKED UP VERSION SHOWING CHANGES MADE TO ABSTRACT

Please replace the abstract with the following:

A system for the production of autologous thrombin, comprising a centrifuge including a blood reservoir for receiving and separating an autologous anticoagulated blood sample having multiple inactive blood components and means for removing at least one of said inactive blood components upon separation, and a dispenser having at least two collection chambers for receiving said at least one of said inactive blood components, wherein a first collection chamber activates a first portion of said inactive blood component and stores the resulting coagulated blood component comprising a clot and said autologous thrombin.

CLEAN VERSION OF AMENDED ABSTRACT

Please replace the abstract with the following:

A system for the production of autologous thrombin, comprising a centrifuge including a blood reservoir for receiving and separating an autologous anticoagulated blood sample having multiple inactive blood components and means for removing at least one of said inactive blood components upon separation, and a dispenser having at least two collection chambers for receiving said at least one of said inactive blood components, wherein a first collection chamber activates a first portion of said inactive blood component and stores the resulting coagulated blood component comprising a clot and said autologous thrombin.

MARKED UP VERSION SHOWING CHANGES MADE TO CLAIMS

Please cancel claims 28-32 and add new claims 33 -52

33. (New) A system for the production of autologous thrombin, comprising:

a centrifuge including a blood reservoir for receiving and separating an autologous anticoagulated blood sample having multiple inactive blood components and means for removing at least one of said inactive blood components upon separation; and

a dispenser having at least two collection chambers for receiving said at least one of said inactive blood components, wherein a first collection chamber activates a first portion of said inactive blood component and stores the resulting coagulated blood component comprising a clot and said autologous thrombin.

34. (New) The system of claim 33, further comprising a filter for separating said autologous thrombin from said clot.

35. (New) The system of claim 33, wherein said anticoagulated blood sample is separated into various inactive blood components comprising a red blood cell component, a white blood cell component, a platelet rich plasma component and a platelet poor plasma component.

36. (New) The system of claim 35, wherein said inactive blood components contain sodium citrate.

37. (New) The system of claim 36, wherein said first collection chamber contains a restoration agent and an activation agent.

38. (New) The system of claim 37, wherein said restoration agent is a calcium salt.

39. (New) The system of claim 38, wherein said calcium salt is calcium chloride, calcium gluconate, or calcium carbonate.

40. (New) The system of claim 37, wherein said activation agent is glass wool, silica, aluminum, diatomaceous earth, kaolin, plastic, siliconized glass, or a chemical activator.

41. (New) The system of claim 35, wherein said anticoagulated blood sample contains heparin.

42. (New) The system of claim 41, wherein said first collection chamber contains a restoration agent and an activation agent.

43. (New) The system of claim 42, wherein said restoration agent is an anti-heparin agent.

44. (New) The system of claim 43, wherein said anti-heparin agent is heparinase or protamine.

45. (New) The system of claim 42, wherein said activation agent is glass wool, silica, aluminum, diatomaceous earth, kaolin, plastic, siliconized glass, or a chemical activator.

46. (New) The system of claim 33, wherein said inactive blood component is platelet rich plasma.

47. (New) The system of claim 46, wherein said platelet rich plasma in said first collection chamber coagulates as a result of being activated and the coagulated platelet rich plasma is triturated thereby expressing said autologous thrombin.

48. (New) The system of claim 33, wherein said inactive blood component is platelet poor plasma.

49. (New) The system of claim 48, wherein said platelet poor plasma in said first collection chamber coagulates as a result of being activated and the coagulated platelet poor plasma is triturated thereby expressing said autologous thrombin.

50. (New) The system of claim 34, wherein said filter is positioned within said first collection chamber and comprises glass wool which also serves as a contact activator.

51. (New) The system of claim 34, wherein said filter is positioned outside of said first collection chamber and has a pore size that allows said autologous thrombin to pass through said filter but retains said clot and debris from said clot.

52. (New) A system of the production of autologous thrombin, comprising:

a centrifuge including a blood reservoir for receiving and separating an autologous anticoagulated blood sample having multiple inactive blood components;

a lumen for transferring at least of said one inactive blood component from said blood reservoir to a dispenser upon separation, said dispenser having at least two collection chambers wherein a first collection chamber activates a first portion of said inactive blood component and stores the resulting coagulated blood component comprising a clot and said autologous thrombin; and

a filter for separating said autologous thrombin from said coagulated blood component.

CLEAN VERSION OF AMENDED CLAIMS

Please cancel claims 28-32 and add new claims 33 -52

33. (New) A system for the production of autologous thrombin, comprising:

a centrifuge including a blood reservoir for receiving and separating an autologous anticoagulated blood sample having multiple inactive blood components and means for removing at least one of said inactive blood components upon separation; and

a dispenser having at least two collection chambers for receiving said at least one of said inactive blood components, wherein a first collection chamber activates a first portion of said inactive blood component and stores the resulting coagulated blood component comprising a clot and said autologous thrombin.

34. (New) The system of claim 33, further comprising a filter for separating said autologous thrombin from said clot.

35. (New) The system of claim 33, wherein said anticoagulated blood sample is separated into various inactive blood components comprising a red blood cell component, a white blood cell component, a platelet rich plasma component and a platelet poor plasma component.

36. (New) The system of claim 35, wherein said inactive blood components contain sodium citrate.

37. (New) The system of claim 36, wherein said first collection chamber contains a restoration agent and an activation agent.

38. (New) The system of claim 37, wherein said restoration agent is a calcium salt.

39. (New) The system of claim 38, wherein said calcium salt is calcium chloride, calcium gluconate, or calcium carbonate.

40. (New) The system of claim 37, wherein said activation agent is glass wool, silica, aluminum, diatomaceous earth, kaolin, plastic, siliconized glass, or a chemical activator.

41. (New) The system of claim 35, wherein said anticoagulated blood sample contains heparin.

42. (New) The system of claim 41, wherein said first collection chamber contains a restoration agent and an activation agent.

43. (New) The system of claim 42, wherein said restoration agent is an anti-heparin agent.

44. (New) The system of claim 43, wherein said anti-heparin agent is heparinase or protamine.

45. (New) The system of claim 42, wherein said activation agent is glass wool, silica, aluminum, diatomaceous earth, kaolin, plastic, siliconized glass, or a chemical activator.

46. (New) The system of claim 33, wherein said inactive blood component is platelet rich plasma.

47. (New) The system of claim 46, wherein said platelet rich plasma in said first collection chamber coagulates as a result of being activated and the coagulated platelet rich plasma is triturated thereby expressing said autologous thrombin.

48. (New) The system of claim 33, wherein said inactive blood component is platelet poor plasma.

49. (New) The system of claim 48, wherein said platelet poor plasma in said first collection chamber coagulates as a result of being activated and the coagulated platelet poor plasma is triturated thereby expressing said autologous thrombin.

50. (New) The system of claim 34, wherein said filter is positioned within said first collection chamber and comprises glass wool which also serves as a contact activator.

51. (New) The system of claim 34, wherein said filter is positioned outside of said first collection chamber and has a pore size that allows said autologous thrombin to pass through said filter but retains said clot and debris from said clot.

52. (New) A system of the production of autologous thrombin, comprising:

a centrifuge including a blood reservoir for receiving and separating an autologous anticoagulated blood sample having multiple inactive blood components;

a lumen for transferring at least of said one inactive blood component from said blood reservoir to a dispenser upon separation, said dispenser having at least two collection chambers wherein a first collection chamber activates a first portion of said inactive blood component and stores the resulting coagulated blood component comprising a clot and said autologous thrombin; and

a filter for separating said autologous thrombin from said coagulated blood component.